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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,581	11/09/2000	Ronald S. Vladyka JR.	FMC-1006US	2095

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/06/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/708,581

Applicant(s)

VLADYKA ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 14-16 and 20-26 are rejected under 35 U.S.C. 102(e) as being anticipated by McTeigue et al (US Patent No. 6,149,943).

The McTeigue et al patent discloses microcrystalline cellulose particles having a particle size up to about 220 microns (see column 1, line 54) and bulk density from about 0.40 grams/cubic centimeters (see column 2, lines 51 and 52), which anticipates the microcrystalline cellulose granules of the instant claims. The McTeigue et al patent also disclose coating compositions, which may include the polymer systems disclose in the Table at lines 40-67 of column 4. The polymer systems disclosed by McTeigue et al include coatings that are analogous to some of the hydrocolloids set forth in instant Claims 21-23. McTeigue et al further disclose preparations that involve combining coated particles with excipients, which are compressed to form tablets (see column 6, 2<sup>nd</sup> paragraph). Also see Examples 1 and 2 of the McTeigue et al patent whereby the examples disclose compositions comprising analogous microcrystalline cellulose granules, hydrocolloid, excipient and active ingredients that anticipates the instantly claimed invention.

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3. Claims 14-17 and 20-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kumar (US Patent No. 6,117,451).

The Kumar patent discloses microcrystalline cellulose that is highly compressible and produces hard, strong tablets at a low machine pressure. The Kumar patent discloses microcrystalline cellulose that may have a particles size of 200 microns and a density range of 0.20 to .45 g/ml (see column 9, 3<sup>rd</sup> paragraph), which anticipates the microcrystalline cellulose granules of the instant claims. See the table at lines 6-17 of column 10 for a list of excipients that may be present in a composition with microcrystalline cellulose and their approximate amounts. Also see the table in Example 1 of the Kumar patent, which represents a basic compression formulation of Metformin HCl 500 mg tablets. The information disclosed in column 10, lines 6-17 and Example 1 anticipate the present of hydrocolloid with the microcrystalline cellulose granules of instant Claims 20-23 and tablet of instant Claims 24-26.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharnejad et al (US Patent No. 6,123,964) in view of Erkoboni et al (US Patent No. 5,725,886).

Applicants claim a method for preparing microcrystalline cellulose granules as set forth in instant Claim 1.

The Asgharnejad et al patent discloses a process comprising the steps that involves (1) forming a powder blend of the active ingredient with a binder/diluent, a first diluent, a second diluent, and a disintegrant, using a mixer; (2) wet granulating the powder blend by adding a solution of ethanol/water to the powder blend; (3) drying the granules to remove the ethanol/water with heated air in a fluid bed dryer or tray dryer (see column 2, line 63 to column 3, line 6). See column 3, lines 21-29 of the Asgharnejad et al patent wherein the binder/diluent is pregelatinized starch; the first diluent is microcrystalline cellulose; and wherein it is indicated that the solution of ethanol/water is in a range of 0% to 80% ethanol in water (w/w). The ethanol/water solution used in the Asgharnejad et al patent meets the polar organic solvent requirement disclosed in the claims and the pregelatinized starch that is disclosed in the Asgharnejad et al patent embraces the present of the hydrocolloid in the instantly claimed process. The Asgharnejad et al patent further disclose the present of an active ingredient as part the process medium and include steps that lead to the preparation of a tablet that is not set forth in the instantly claimed method. However, the active ingredient and additional process steps does not negate the preparation of microcrystalline cellulose granules in the Asgharnejad et al patent. The Erkoboni et al patent shows that the other hydrocolloids that are disclosed in the instant claims (see instant Claims 11 and 12) are well known in the art. The Erkoboni et al patent discloses microcrystalline cellulose-hydrocolloid compositions and set forth examples of hydrocolloids in the paragraph bridging column 2 and column 3 of the patent that embraces the listed hydrocolloids in instant Claims 11 and 12. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the starch compound used in the process of the Asgharnejad et al with a

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hydrocolloid in view of the recognition in the art, as evidenced by the Erkoboni et al patent, that use of hydrocolloids in the preparation of a microcrystalline cellulose product are effective for forming an aqueous solution or dispersion.

7. Claims 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar (US Patent No. 6,117,451) in view of Kamada (US Patent No. 5,384,130).

The Kumar patent discloses microcrystalline cellulose that is highly compressible and produces hard, strong tablets at a low machine pressure. Kumar discloses microcrystalline cellulose that may have a particles size of 200 microns and a density range of 0.20 to .45 g/ml (see column 9, 3<sup>rd</sup> paragraph), which is similar to the microcrystalline cellulose granules of the instant claims. See the table at lines 6-17 of column 10 for a list of excepients that may be present in a composition with microcrystalline cellulose and their approximate amounts. Also see the table in Example 1 at column 10 of the Kumar patent, which represent a basic compression formulation of Metformin HCl 500 mg tablets. The information disclosed in column 10, lines 6-17 and Example 1 embraces the present of hydrocolloid with the microcrystalline cellulose granules of instant Claims 20-23 and tablet of instant Claims 24-26. The instant claims differ from the Kumar patent by disclosing microcrystalline cellulose granules that have particles sizes of from 250-1000 microns, which is not indicated in the Kumar patent. However, the Kamada patent shows that microcrystalline cellulose granules that have particles sizes within the claimed ranged is well known in the art. Kamada discloses microcrystalline cellulose granules whereby their spherical seed cores have an average particle size of 100 to 1000  $\mu\text{m}$  (see the abstract of the Kamada patent). It would have been obvious to modify the pharmaceutical preparation of Kumar patent by substituting for the microcrystalline cellulose thereof, a microcrystalline cellulose that has a particle size from 250 to 1000 microns as taught by the Kamada patent, since the Kamada patent suggests that such microcrystalline cellulose allows for improve stability of active ingredients.

8. **Summary:** All the claims are rejected.

***Examiner's Telephone Number, Fax Number, and Other Information***

9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

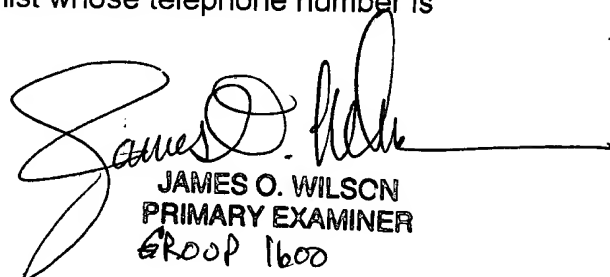
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*

E. White

  
JAMES O. WILSON  
PRIMARY EXAMINER  
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